# EXHIBIT A

# REDACTED

# IN ITS ENTIRETY

# EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

**CONFIDENTIAL-FILED UNDER SEAL**

| | |
|---|---|
| IN RE TRICOR DIRECT PURCHASER ANTITRUST LITIGATION | Civil Action No. 05-340 KAJ |
| THIS DOCUMENT RELATES TO:<br><br>ALL ACTIONS<br>C.A. NOS. 05-340, 05-404, 05-605 (KAJ) | Hon Kent Jordan, U.S.D.J. |

# DECLARATION OF JEFFREY J. LEITZINGER, PH.D.

**Econ One Research, Inc.**

**May 8, 2006**

5th Floor
601 W. 5th Street
Los Angeles, California 90071
(213) 624-9600
fax: (213) 624-6994

Suite 2825
Three Allen Center
333 Clay Street
Houston, Texas 77002
(713) 228-2700
fax: (713) 228-3296

Suite 1170
1215 K Street
Sacramento, California 95814
(916) 449-2860
fax: (916) 449-2870

Suite 230
106 E. 6th Street
Austin, Texas 78701
(512) 476-3711
(512) 476-9712

## I. Introduction and Qualifications

I am an economist and President of Econ One, an economic research and consulting firm with offices in Los Angeles, Sacramento, Austin, and Houston. I have masters and doctoral degrees in economics from UCLA and a bachelor's degree in economics from Santa Clara University. While at UCLA, one of my areas of concentration was industrial organization, which involves the study of markets, competition, antitrust and other forms of regulation.

During the past 25 years of my professional career, industrial organization has remained the principal focus of much of my work. In that regard, I also have worked on numerous projects relating to antitrust economics. I have worked extensively on issues involving market power, market definition, and the competitive effects of firm behavior. I have frequently assessed damages resulting from anticompetitive conduct and have substantial experience in the calculation of damages in class action litigation. I also have significant experience with economic issues related to class certification in antitrust contexts.

I have testified as an expert economist in State and Federal Courts and before a number of regulatory commissions. A more detailed summary of my training, past experience and prior testimony is shown in Exhibit 1.

In regards to the pharmaceutical industry, I am familiar with the economic and academic literature on the subject of generic competition and impaired generic competition. I also have specific experience in making economic assessments of the effects of AB-rated generic competition in pharmaceutical markets. For instance, I have previously analyzed impact and damages issues, as well as issues relating to the allocation of aggregate damages to individual class members, in a number of antitrust cases that involve allegations very similar to this case—i.e., overcharges to a class of direct purchasers of a brand name drug resulting from impaired generic competition. In the *Cardizem* case (*In re: Cardizem CD Antitrust Litigation*, MDL No. 1278 (E.D. Mich.)), I prepared an analysis of aggregate, classwide damages incurred by a class of direct purchasers for purposes of mediation and settlement. The direct purchaser class case settled for $110 million. I also prepared an analysis regarding the allocation of settlement proceeds among Class members. It is my understanding that the court approved the allocation analysis.

I performed a similar role in the Buspirone case (*In re: Buspirone Patent & Antitrust Litigation*, MDL No. 1413 (S.D.N.Y.)). I prepared a report analyzing aggregate damages to the direct purchaser class and proposing a damages allocation approach, which was submitted to the court in support of approval of the class settlement and allocation plan on April 11, 2003. The court approved a settlement of $220 million for the direct purchaser class. It is my

understanding that the court approved the settlement and my proposed allocation approach as fair and reasonable.

In *North Shore* Hematology-*Oncology Associates, P.C. v. Bristol-Myers Squibb Co.*, (D.D.C.), I prepared a report analyzing aggregate damages and proposing a damages allocation approach. That case reportedly settled for $50 million for a class of direct purchasers. It is my understanding the court approved the settlement and my proposed allocation approach.

I submitted four expert reports on classwide damages and other economic issues in the *Terazosin* case (*In re: Terazosin Hydrochloride Antitrust Litigation*, MDL No. 1317 (S.D. Fla.)) brought on behalf of a class of direct purchasers of the brand name drug Hytrin, sold by Abbott Laboratories, similarly addressing classwide impact and damages due to delayed generic competition. That case settled for nearly $75 million for a class of direct purchasers. For purposes of the settlement I submitted a report setting forth a damages methodology and allocation plan, that was approved by the court.

In *In re: Relafen* Antitrust *Litigation*, Master File 01-12239-WGY (D. Mass.), I submitted three reports in which I evaluated market power under Section 2 of the Sherman Act and relevant market issues, estimated aggregate overcharge damages to the direct purchaser class, and rebutted arguments made by the defense expert relating to class certification. That case settled for $175 million for a class of direct purchasers. For purposes of the settlement, I

submitted a report setting forth the damages methodology I employed, an allocation methodology and the results based upon applying it to the claimant data. The methodology and results were approved by the court.

In *In re: Remeron Direct Purchaser Antitrust Litigation*, No. 03-CV-0085 (D.N.J.), I submitted a report relating to class certification issues. Those issues included the likely impact of a delay in generic competition on a class of direct purchasers of the branded antidepressant Remeron, the availability of economic methodologies and evidence, common to all class members, that would demonstrate impact in the form of overcharges, and whether overcharge damages could be calculated on a classwide, aggregate basis using reliable methodologies. I also submitted an expert report addressing the issues of monopoly power, market definition, and aggregate overcharge damages, and a rebuttal report on those subjects. Finally, I submitted a proposed allocation plan to the Court. In *Remeron* the direct purchaser class settled for $75 million and the Court approved my damages and allocation methodologies as fair and reasonable.

I also served as an expert in the following pertinent cases:

(1) *In re: Ciprofloxacin Hydrochloride Antitrust Litigation*, MDL No. 1383 (E.D.N.Y.). In that case, brought on behalf of a class of direct purchasers of the brand name drug Cipro, I submitted a rebuttal declaration in the class certification proceedings. I also submitted an expert report addressing antitrust

impact and damages flowing from delayed generic competition, and a rebuttal expert report.

(2) *In re: K-Dur Antitrust Litigation*, (D.N.J.). In that case, I have submitted a report relating to class certification issues. In particular, my report addressed the issues of the likely impact on class members of delayed generic competition, the availability of common, classwide economic evidence and methodologies that would demonstrate classwide impact in the form of overcharges, and whether those damages could be calculated as a whole on an aggregate basis using reliable methodologies.

(3) *In re: Nifedipine* Antitrust *Litigation*, (D.D.C.). In that case I have submitted a report and a rebuttal report relating to class certification issues, including the availability of classwide economic evidence and methodologies to prove impact and aggregate overcharge damages.

Econ One is being compensated for the time I spend on this matter at my normal and customary rate of $525 per hour. Econ One also is being compensated for time spent by my research staff on this project at their normal and customary hourly rates.

## II. Factual Overview

I understand that a Complaint in this matter was filed as a class action on behalf of Louisiana Wholesale Drug Company, Inc., Rochester Drug

Co-Operative, Inc., Meijer, Inc. and Meijer Distribution, Inc. ("Plaintiffs"),[1] direct purchasers of the prescription drug TriCor,[2] "a drug used to control levels of cholesterol and triglycerides in humans"[3] from Abbott Laboratories ("Abbott"), Fournier Industrie et Santé, and Laboratoires Fournier S.A. (jointly "Fournier") (collectively "Defendants").[4] Defendants have manufactured and/or sold TriCor in the U.S. since 1998.[5] [redacted]

REDACTED

The Complaint alleges that, in response to "the substantial threat to their monopoly profits posed by the potential onset of competition from generic versions of TriCor,"[8] Defendants conspired and "concocted a multifaceted scheme," which permitted them "to maintain and extend their monopoly power in the fenofibrate market by improperly preventing generic manufacturers from effectively competing with TriCor."[9] According to Plaintiffs, Defendants first

[1] The Complaint to which I refer is dated September 23, 2005 and is entitled "Direct Purchaser Class Plaintiffs' First Amended and Consolidated Class Action Complaint." I shall refer to it simply as the "Complaint."
[2] TriCor is the brand name under which Abbott sells the molecule fenofibrate.
[3] Complaint ¶ 1.
[4] The "Class" is defined in the Complaint as: "All persons or entities in the United States who purchased TriCor in any form directly from any of the Defendants at any time during the period April 9, 2002 through the present." The Class excludes "Defendants, and their officers, directors, management, employees, subsidiaries, or affiliates, and all federal governmental entities." Complaint ¶ 21.
[5] Complaint ¶ 2.
[6] Abbott_Tricor00001933.
[7] Abbott_Tricor00001856-1857, Abbott_Tricor00001862. Also see Abbott_Tricor00006407.
[8] Complaint ¶ 2.
[9] Complaint ¶ 3.

employed their anticompetitive scheme to impede and impair competition from generic fenofibrate capsules;[10] subsequently, they utilized the same scheme again to impede and impair competition from generic fenofibrate tablets.[11]

Defendants' scheme allegedly involved: (1) baseless patent infringement lawsuits designed to delay market entry of generic versions of fenofibrate and (2) various actions designed during the course of that period of delay to shift the existing prescription base away from TriCor versions that were about to face generic competition to new versions of TriCor (no more effective or beneficial than the old version) for which a generic had yet to be developed and could not, therefore, reach the market for some time.[12] Plaintiffs allege that the purpose and effect of this scheme was to block the competitive price benefits that unimpeded automatic generic substitution would otherwise have created by, among other things, preventing pharmacies from automatically substituting lower-priced generic equivalents for TriCor. Plaintiffs allege that Defendants' scheme was an effort to maintain monopoly power over fenofibrate.[13]

---

[10] For example, see Complaint ¶¶ 4-7. Plaintiffs refer in the Complaint to TriCor capsules as "TriCor A."

[11] For example, see Complaint ¶¶ 8-9. Plaintiffs refer in the Complaint to TriCor tablets as "TriCor B."

[12] See Complaint ¶¶ 4-10, 46-146.

[13] Complaint ¶¶ 5-13, 41, 48-49, 81-83, 92-95, 114-117, 150-154, 163-166, 176-179. According to one Abbott internal document:

REDACTED

Abbott_Tricor00000718.

## III. Assignment

I have been asked to assume that, but for Defendants' conduct, there would have been an AB-rated[14] generic version of TriCor *capsules* available in the market on or before April 9, 2002[15] and an AB-rated generic version of TriCor *tablets* in the market on or before March 5, 2004.[16] Given these assumptions, I have been asked to form an opinion about the likely impact of Defendants' conduct on prices paid for fenofibrate by Class members. I also have been asked to determine whether the existence of that impact as to all (or nearly all) Class members will be demonstrable at the time of trial without need for individualized inquiry as to the circumstances of each Class member. And lastly, assuming, as Plaintiffs contend, that this impact involves an overcharge, I have been asked to determine whether overcharge damages can be calculated for the Class as a whole on an aggregate basis using a reliable methodology.

I have reviewed the Complaint, documents produced in discovery by Abbott, Fournier, Teva Pharmaceuticals USA, Inc. ("Teva"), and Impax Laboratories, Inc. ("Impax"), publicly available data, transactional data supplied

---

[14] "AB rated" is a term the FDA uses to classify drug products (e.g., a generic version of a branded drug) that have been found to be therapeutically equivalent (to the branded counterpart). An AB rated generic may be freely substituted for its branded counterpart at the pharmacy level without the prescribing physician's permission in most states. Therapeutically equivalent is a technical term for products that meet certain criteria including safety and efficacy, "pharmaceutical equivalence," "bioequivalence," labeling and manufacturing standards. The FDA lists such substitutable drugs in its "Orange Book," the formal title of which is *Approved Drug Products With Therapeutic Equivalence Indications*. The definitions of therapeutic equivalence, pharmaceutical equivalence, and bioequivalence are listed in Sections 1.2 and 1.7.

[15] Complaint ¶ 155.

[16] *Ibid.* Plaintiffs suggest there may be some interplay between these scenarios. Complaint ¶ 114. Even if true, that does not affect my analysis or my opinion.

by Abbott, and sales data obtained from IMS Health ("IMS").[17] A list of the materials I and/or my staff have reviewed is attached as Exhibit 2. As discovery is ongoing, I intend to continue to review documents and data as they are made available.

In summary, I have concluded, first, that the impairment of generic competition in the manner alleged in this case would prevent Class members from gaining most of the competitive benefit that AB-rated generic competition would otherwise be expected to have provided in the form of lower fenofibrate prices. This benefit is predictable, substantial and market-wide. Thus, determining the effects upon Class Members from being deprived of that competition lends itself naturally to a classwide analysis.

Regarding classwide proof of impact, there is a well-documented history surrounding the competitive effects of unimpeded generic competition in pharmaceutical markets generally. The same conclusion is borne out in: 1) economic literature and empirical evidence regarding generic competition; 2) [redacted] REDACTED [redacted]; and 3) pricing data showing the experience in dozens of markets following generic entry. All of this evidence is common—i.e., the same—across members of the proposed Class.

[17] IMS provides market data tracking sales of prescription drugs, measured in dollars and units. Mr. Fiske, Director of Pricing and Planning of Abbott's Pharmaceuticals Products Division, [redacted] Fiske Deposition, pp. 206-207.



REDACTED

Further, combining the size and scope of these competitive benefits with the fact that most, if not all, Class members are broad-line resellers whose product needs will be affected by significant changes in market-wide consumption patterns, I conclude that the restriction on generic entry at issue in this case would broadly affect all or nearly all members of the proposed Class. Proof of impact for the Class would then consist of (1) evidence about the substantial size and market-wide scope of generic price impacts and (2) evidence about the pharmaceutical distribution system and the likely relationship between market-wide changes in prices and purchase patterns and those experienced by the Class. This manner of proof does not require individualized Class member inquiries.

Finally, having now performed the analysis in more than half a dozen other matters involving assessing damages to a class of direct purchasers flowing from impeded or delayed generic competition, I am confident that the calculation of aggregate overcharges for the Class in this case will be readily susceptible to formulaic analysis that does not require individualized inquiry as to each Class member. In the course of my past work, I have had first-hand experience with economic models and methodologies that can reliably measure the aggregate overcharge to the Class—several of which methods have been

accepted by the presiding courts in resolving the underlying controversies and compensating class members.[18]

## IV. The Fenofibrate Market

### A. TriCor

TriCor is Abbott's branded version of the drug fenofibrate. Fenofibrate is a drug prescribed to treat high levels of cholesterol and triglycerides. Abbott launched branded TriCor capsules in 1998 in 67 mg, and later in 134 mg and 200 mg strengths.[19] On September 4, 2001, the FDA approved TriCor in a tablet formulation, in 54 mg and 160 mg strengths.[20]

According to Plaintiffs, the FDA found that the TriCor tablets were "bioequivalent" to the TriCor capsules.[21] In fact, Plaintiffs allege that Abbott did not conduct separate/independent studies of the safety and efficacy of the TriCor tablets, but rather simply obtained approval on their tablets by establishing that

---

[18] *In re: Cardizem CD Antitrust Litigation*, MDL No. 1278 (E.D. Mich.); *In re: Buspirone Patent & Antitrust Litigation*, MDL No. 1413 (S.D.N.Y.); *North Shore* Hematology-*Oncology Associates, P.C. v. Bristol-Myers Squibb Co.*, (D.D.C.); *In re: Terazosin Hydrochloride Antitrust Litigation*, MDL No. 1317 (S.D. Fla.); *In re: Relafen* Antitrust *Litigation*, Master File 01-12239-WGY (D. Mass.) and *In re: Remeron Direct Purchaser Antitrust Litigation*, No. 03-CV-0085 (D.N.J.).

[19] The 67 mg capsule was approved by the FDA in February 1998. The 134 mg and 200 mg capsules were approved in June 1999. Complaint ¶ 46.

[20] Complaint ¶ 80.

[21] Complaint ¶¶ 87-89. "Bioequivalence refers to equivalent release of the same drug substance from two or more drug products or formulations." Orange Book, Section 1.3. This involves a technical demonstration that the two tested drugs are absorbed at the same rate and to the same extent. Orange Book Section 1.2.

the tablets were bioequivalent to the capsules.[22] Abbott stopped selling the branded capsules when it began selling the tablets.[23]

Abbott subsequently received approval in November 2004 for two new tablet strengths (48 mg and 145 mg, called the "NFE" tablets).[24] Abbott then stopped selling the tablets when it began selling, and converting the market to, the NFE tablets.[25] [redacted][26] [redacted] REDACTED [redacted] I explain why this is so below.

**B. Generic Competition**

In order to obtain an AB rating from the FDA, a generic drug must be therapeutically equivalent to an existing FDA-approved branded product for that product's FDA-approved uses. AB-rated generics provide the same efficacy

[22] Complaint ¶¶ 4, 87, 157.
[23] Complaint ¶¶ 80-82. [redacted] Fiske Deposition, pp. 74, 293.
[24] Orange Book. In addition to the difference in strengths, this tablet formulation could be taken without food. "NFE" stands for "no food effect." Abbott_Tricor00005626.
[25] Complaint ¶ 112; Fiske Deposition, p. 92. [redacted]
[26] Abbott_Tricor00005816, Abbott_Tricor00001862.
[27] Abbott_Tricor00000718-720, Abbott_Tricor00001855-1856, 1862, 1873; Abbott_Tricor00001242.

REDACTED

and safety as their corresponding branded drugs, but at lower price. Thus, AB-rated generics play a critical (and unique) role in U.S. pharmaceutical markets, providing direct, price-related competition to branded drugs. For AB-rated generics, most of the brand's market is susceptible to competitive (and often automatic) substitution. State laws allow (and in some cases, require) pharmacists to switch patients who have a prescription for the brand product to AB-rated generics.[28]

[redacted][29]

REDACTED

[redacted].[30] Here, too, the substitution process operates much less effectively without the AB rating.

Under the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), generic drug manufacturers are allowed to file an Abbreviated New Drug Application ("ANDA"), which permits these manufacturers to rely on basic research supporting the safety and efficacy of the original or

[28] It is my understanding that in all 50 states, the pharmacist need not obtain the prescribing physician's permission to substitute an approved generic even where the prescription is for the branded version of the drug (unless that prescription is specifically written for "brand only").

[29] See, for example, Abbott_Tricor00001218 ([redacted]). As Mr. Fiske of Abbott testified [redacted] Fiske Deposition, p. 232. [redacted]

[30] Fiske Deposition, pp. 43-44. Mr. Fiske testified that [redacted]

REDACTED

"pioneer" version of the drug. This streamlined application process allows generic drugs to come to market in an expedited fashion. When filing an ANDA for a drug that is still claimed by the brand manufacturer in the Orange Book to be covered by a patent, the applicant must file a "Paragraph IV Certification" with the FDA and notify the patent holder of the application. The patent holder then has 45 days to file a patent infringement suit against the ANDA applicant. If a patent infringement claim is filed, the ANDA cannot be approved until the earliest of 30 months, the patent's expiration, or the resolution of any court proceeding declaring the patent not infringed or invalid. A separate ANDA is required for each dosage form of a drug entity.

The Hatch-Waxman Act provides a 180-day exclusivity period for the first ANDA filer who includes a Paragraph IV Certification. No other manufacturer can receive final FDA approval to market the generic product specified in its ANDA until the termination of the 180-day exclusivity period. The exclusivity period begins to run at the earlier of the date the first ANDA filer begins marketing its products or the date at which the infringement claims are resolved such that entry of the generic can occur.

### C. Allegations Regarding Defendants' Anticompetitive Conduct

Plaintiffs allege, and I take as true for purposes of this Declaration, that Defendants engaged in a scheme to impair and impede generic competition[31] that involved the following steps:

(1) Modifying Abbott's existing TriCor products to new versions, which were not improvements upon the existing versions, but to which pending generic ANDAs would not be AB-rated (i.e., automatically substitutable).[32]

(2) Halting the sale of the old TriCor versions, and then converting market demand for fenofibrate to the new TriCor versions to which the pending generic ANDAs were not AB-rated.[33]

(3) Taking several steps (often involving significant costs)[34] to convert the existing TriCor prescription base to new versions that did not face the near-term prospect AB-rated generics. These steps included (a) halting sales of the existing version, (b) "bleeding down" its inventories and the inventories of TriCor resellers, (c) buying back and destroying inventory, and (d) revising returned-goods policies to eliminate old versions from the distribution channel.[35]

(4) Falsely claiming that the new branded TriCor version was superior to, or an improvement over, the existing TriCor product.[36]

(5) And, using sham patent infringement litigation to "buy time" to effectuate these steps, before pending generic applicants for

[redacted]

[31] [redacted] Fiske Deposition p. 298.
[32] Complaint ¶¶ 4, 6-8, 79-80, 89, 106-09.
[33] Complaint ¶¶ 5(a), 81, 90, 112(a), (b).
[34] Complaint ¶¶ 90-91, 157. Mr. Fiske [redacted] Fiske Deposition, pp. 264-266.
[35] Complaint ¶¶ 5(c), 48, 82-85, 112(b), (c). Abbott's Mr. Fiske [redacted] Fiske Deposition, at 224.
[36] Complaint ¶¶ 87-88.

REDACTED

the existing TriCor version could be approved and enter the market.[37]

Plaintiffs claim that these tactics succeeded in impairing generic competition to branded TriCor by impeding the process of generic substitution and thereby preventing FDA-approved TriCor generics from materially penetrating the fenofibrate market.[38] Plaintiffs allege that these tactics purposely left the newly-launched generic without any corresponding branded product market.[39]

## V. Antitrust Impact

One key economic impact of conduct that impairs generic competition is that prices paid by direct purchasers of the drug product remain artificially high—which is to say, direct purchasers incur overcharges. This happens in several ways. Impediments to generic competition prevent substitution of lower-priced generic for the brand. And, because such

[37] Complaint ¶¶ 5(b), 9, 48, 62-77, 96-103, 120-146, 164, 177.
[38] Complaint ¶¶ 7, 49, 76, 113-115.
[39] According to one document produced in this case, [redacted] FOURNIER/FTC 0001958.

impediments limit competitive pressure on the brand's sales, they also limit the depth and frequency of discounts and/or price reductions for the brand. Finally, limits on the extent of generic competition prop up prices for the volume of generic sales that do manage to reach the market.

If it is true, as alleged in this case, that the Defendants' conduct greatly limited generic competition, I would expect that all (or nearly all) of the proposed Class members experienced some amount of overcharge stemming from one or more of these three effects. My conclusion in this regard is grounded in two further observations about generic competition and the pharmaceutical industry. First, generic competition is a broad and powerful instrument for bringing down prices. Typically, within a relatively short time period, unfettered generic competition converts the vast majority of the market to generic products carrying a price less than a third of what the brand used to command. The remaining few buyers that stay with the brand often do so because they are offered substantial discounts.

Second, the Class members in this case are, for the most part, middlemen and/or resellers in the drug distribution system serving market cross sections. The broad market switching and price reductions that generic competition produces invariably reach at least most of the customers/patients these middlemen serve. Hence, Class members buy generic product and pay generic prices to serve some or all of their customers; they also purchase highly

discounted brand volumes for at least some of the limited numbers of their customers that stay with the brand. Having now been involved in a number of generic competition cases well into full discovery and analysis of the merits, I have yet to see an instance in which there was any material number of direct purchasers that were not generic customers, or would not have been generic customers had that competition been unimpeded or did not receive substantial price discounts from the brand in order to remain loyal brand customers. Classwide proof of impact would therefore include the following types of evidence.

### A. Economic Literature and Empirical Evidence Regarding The Effects of Generic Competition

There is an extensive body of published research concerning the effects of generic competition in pharmaceutical markets. The principal conclusions of this research are that AB-rated generic products: (1) enter the market at substantially lower prices than their brand counterparts; and (2) capture a significant share of the combined product (brand + AB-rated generic) unit sales. Several studies also have found that both the price differential (generic versus the corresponding brand) and the generic's share of sales increase over time, following a similar pattern from market to market. Recent work further demonstrates that generic competition produces lower net prices for the brand as well.

Some of the studies that comprise this research include:

1. U.S. Food and Drug Administration, *The Pediatric Exclusivity Provision: January 2001 Status Report to Congress*, January 2001.

2. Kirking, D.M., F.J. Ascione, C.A. Gaither, and L.S. Welage, *Economics and Structure of the Generic Pharmaceutical Industry*, Journal of the American Pharmaceutical Association, 41; 578-584, 2001.

3. Rozek, R. P., and R. Berkowitz, *The Costs to the U.S. Health Care System of Extending Marketing Exclusivity to Taxol®*, Journal of Research in Pharmaceutical Economics, v. 9, no. 4, 1999, pp. 21-40.

4. Congressional Budget Office, *How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry*, July 1998. ("CBO Study")

5. Bae, J. B., *Drug Patent Expirations and the Speed of Generic Entry*, Health Services Research, Vol. 32, No. 1, pp. 87-101, April 1997.

6. Frank, R. and D. Salkever, *Generic Entry and the Pricing of Pharmaceuticals*, Journal of Economics and Management Strategy, v. 6, no. 1, Spring 1997, pp. 75-90.

7. Grabowski, H. and J. M. Vernon, *Longer Patents for Increased Generic Competition in the US*, PharmacoEconomics, v. 10, suppl. 2, 1996, pp. 110-123.

8. Suh, Dong Churl, *Effect of Multiple Source Entry on Price Competition After Patent Expiration in the Pharmaceutical Industry*, University of Minnesota Ph.D. Dissertation, November 1993.

9. Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks and Rewards*, OTA-H-522, February 1993.

10. Grabowski, H. and J. M. Vernon, *Brand Loyalty, Entry, and Price Competition in Pharmaceuticals after the 1984 Drug Act*, Journal of Law and Economics, v. XXXV, October 1992, pp. 331-350.

11. Caves, Richard E, Michael D. Whinston, and Mark A. Hurwitz, *Patent Expiration, Entry, and Competition in the U.S.*

*Pharmaceutical Industry*, Brookings Papers on Economic Activity: Microeconomics, 1991, pp. 1-66.

12. Wiggins, Steven N. and Robert Maness, *Price Competition in Pharmaceuticals: The Case of Anti-Infectives*, Economic Inquiry, 2004.

13. Reiffen, David and Michael Ward, *Generic Drug Industry Dynamics*, The Review of Economics and Statistics, February 2005, 87(1): 37-49.

14. Federal Drug Administration, *Generic Competition and Drug Prices*, April 4, 2006.

The 1998 CBO Study offers a comprehensive look at the economic effects of generic competition. This study used a large data set, representing about 70 percent of all prescription drugs sold through U.S. retail pharmacies in 1994. The data set included 21 drugs that faced generic competition between 1991 and 1993. The study found that, "[d]uring the first full calendar year in which those 21 drugs faced generic competition. . . [g]enerics . . . cost one-fourth less than the brand-name drugs, on average, at retail prices."[40]

The CBO Study also calculated average retail prices for generic and brand pharmaceuticals in 1994. The study reported that the average retail price for a single source drug was $53.80 versus $17.40 for a generic retail prescription, a difference of over 65 percent.[41]

A study by Grabowski and Vernon, Longer Patents for Increased Generic Competition in the U.S., PharmacoEconomics v. 10, suppl. 2 (pp. 110-

[40] CBO Study, p. 28.
[41] *Ibid.*, p. 15.

123) (1996), compared prices of brand drugs whose patents expired between 1984 and 1991 (the data continued through 1993). The authors found that within one year following generic entry, the generic fell to less than 50 percent of the brand price. After two years of generic competition, the generic price in each case was less than 40 percent of the brand.

A more recent study by Kirking, Ascione, Gaither, and Welage, Economics and Structure of the Generic Pharmaceutical Industry, Journal of the American Pharmaceutical Association, 41: 578-584 (2001), reported that the differential between average generic and average brand prescriptions had increased:

> In 1993 the average cost for a brandname prescription was about 275% higher than the average generic ($35.28 versus $12.82). (cite omitted) By 2000 this difference had grown to nearly 340% ($65.29 versus $19.33) (p. 579).

A very recent study (April 2006) by the U.S. Food and Drug Administration concluded that generic products provide lower prices, with the second generic entrant driving prices down to just over half the price of the brand product. Prices continue to drop as more generics enter the market.[42]

These studies also show that once generic competition begins, a large portion of the market quickly switches over to the generic product. Within its data set of 21 drugs that faced generic competition between 1991 and 1993,

---

[42] FDA, *Generic Competition and Drug Prices*, April 4, 2006. http://www.fda.gov/cder/ogd/generic_competition.htm

the CBO found that within the first year generics captured on average 44 percent of the prescriptions.[43]

The rate of generic penetration has increased over time. Grabowski and Vernon (1996), using the same three time periods discussed above, found that after 1 year of entry the generic share of unit sales was:

| | |
|---|---|
| 1984-1985 | 32 percent |
| 1986-1987 | 38 percent |
| 1989-1991 | 41 percent |
| 1991-1992 | 61 percent |

The 1991-1992 data also showed that within 18 months following entry, the generic share reached 72 percent of the unit sales of the drug entity (or molecule).[44] The authors concluded that:

> Our analysis of major new drugs coming off patent indicates that the extent of generic competition has continued to accelerate in recent years. In particular, drugs that have come off patent since 1991 experienced unit sales losses to generics of over 50% during the first several months of generic competition. This is a much more rapid rate of loss to generics than was observed for similar drugs coming off patent between 1984 and 1989. [cite omitted][45]

One additional subject that has frequently been addressed in these studies is the effect of generic entry on prices for the brand. Some early work (Grabowski and Vernon (1992), Frank and Salkever (1997)) observed that even

[43] CBO Study, p. 28.
[44] Abbott's Mr. Fiske, testified t[redacted] Fiske Deposition, pp. 16-17.
[45] Grabowski and Vernon (1996), p. 121.

REDACTED

in the face of generic entry, brand prices continued to increase however, Grabowski and Vernon found evidence that for some drugs the rate of brand price growth slowed with generic entry. A more recent study by Wiggins and Maness (2004) found that brand prices decrease upon generic entry.

One difficulty with this early work is that it centered on prices drawn from commercially available data that do not capture all discounts (when compared to the confidential manufacturer transactional data that I have been given access to in numerous cases). The net price paid by customers depends both on the starting list price and the discounts they receive. Working with data including discount levels, the CBO Study found that, "[a] statistical analysis of pharmaceutical prices shows that purchasers tend to obtain higher discounts from manufacturers on brand-name drugs when generic substitutes are available[.]"[46] The CBO concluded that when two or more generic manufacturers were competing with a brand, discounts off the brand price were 10 to 17 percent greater.[47] The CBO concluded that "[o]n a selective basis . . . manufacturers of brand name drugs do offer discounts and rebates to some purchasers, and those discounts tend to be larger when generic versions of the drug are available."[48]

Overall, then, this literature clearly establishes that, upon their entry into the market, AB-rated generic drugs sell at a substantial discount to brand

[46] CBO Study, p. 24.
[47] *Ibid.*, p. 29.
[48] *Ibid.*, p. 35.

drugs and that the generic price advantage generally continues to grow over time until an equilibrium point is reached. This literature also demonstrates that AB-rated generic products, when not competitively impaired, capture significant unit sales, and hence market share, from their equivalent brand-name products following the inception of generic competition—exactly the sort of powerful substitution effect between AB-rated generics and their corresponding brand-name drugs that is alleged in the Complaint.[49]

The literature also shows that purchasers are often able to obtain substantially larger discounts and rebates on brand-name drugs following generic entry. Putting the various pieces of the literature together, unimpeded competition from AB-rated generic TriCor sellers would be expected to bring substantially lower prices to purchasers of the product (whether in generic or branded form). The absence of these savings, and the overcharge that results, gives rise to the classwide antitrust impact associated with Plaintiffs' allegations. This research literature is clearly evidence that is common to all members of the Class.

### B. The Manufacturers' Internal Generic Penetration Models and Forecasts

The expected effects of unimpeded AB-rated generic entry [redacted] were

REDACTED

[49] Complaint ¶ 41.

analyzed in [redacted][50] and in the documents of would-be generic competitors Teva and Impax. These analyses offer another source of evidence that can be used to prove the classwide impact of Defendants' scheme.

For instance, in a document entitled [redacted]

[redacted][52]

REDACTED

[redacted]

REDACTED

[redacted]

[50] Mr. Fiske testified [redacted] Fiske Deposition, p. 61.
[51] Abbott_Tricor00005633-5658.
[52] *Ibid.*, at 5634. [redacted] Fiske Deposition, p. 226.
[53] Generic "incursion" (or "penetration") is the percentage of sales of the branded drug entity and its AB-rated generic equivalents that are captured by the generic (and thus lost by the brand).

[redacted]

REDACTED

[redacted]

[54]

[redacted]

[55]

[redacted]

REDACTED

[redacted]

[56]

[redacted]

[54]

[redacted]

REDACTED

[56] Abbott_Tricor00000935-962.
[55] Abbott_Tricor00000937.

[redacted][57]

REDACTED

[redacted][58,59]

[redacted][60]

[redacted]

REDACTED

[redacted][61]

[redacted][62]

[57] Abbott_Tricor0000938-946.
[58] Abbott_Tricor00000939. [redacted] Fiske Deposition, p. 177.

[redacted] Abbott_Tricor00000945. [redacted]

REDACTED

[redacted] (Abbott_Tricor0000946). Mr. Fiske of Abbott [redacted]

[redacted] Fiske Deposition, pp. 200, 204.
[60] Abbott_Tricor00012660-12726. See in particular page -12719.
[61] Abbott_Tricor00012715.
[62] [redacted] Abbott_Tricor00012720.

[redacted]

REDACTED

[redacted]

REDACTED

[redacted]

REDACTED

[redacted]

[53] Abbott_Tricor00006407-8.
[54] Abbott_Tricor00006406 d
[55] Abbott_Tricor00004892.

REDACTED

REDACTED

REDACTED

REDACTED

[65] Abbott_Tricor00000719.

Impax, which had filed ANDAs seeking to market generic TriCor capsules, and later tablets, performed several projections that show [redacted]

[redacted][67] In a forecast Impax [redacted]

REDACTED

[redacted][68] I have seen several similar forecasts by Impax, [redacted]

REDACTED

[redacted][70]

[67] [redacted] IMPAX258167.

[68] *Ibid.*

[70] For example, IMPAX258171 ([redacted]), IMPAX258211-212 ([redacted] REDACTED [redacted] IMPAX258336-337 ([redacted]. See, e.g., IMPAX258288-291.

Teva prepared similar forecasts. [redacted]

[redacted] REDACTED [redacted][71]

[redacted][72]

Abbott's pre-generic-entry price. [redacted]

[redacted] REDACTED [redacted][73]

[71] Teva-TriCor 039431.

[72] [redacted] REDACTED [redacted] (MPAX258167). [redacted] Teva-TriCor 039413-414.

These internal analyses [redacted] REDACTED [redacted] The consistent message from these studies [redacted] REDACTED [redacted] Thus, to the extent Defendants were able to convert prescription volume to a new version of the branded product that does not have an AB-rated generic, they were able to forestall these competitive effects–that is to say, Defendants were able to force substantial overcharges broadly across the market. And, here again, this evidence is common to members of the Class.

### C. Data Reflecting Generic Competition to Other Branded Drugs

Another way to show the market effects of generic competition is through pricing data (published by IMS) for a variety of brand products that have experienced generic competition. This, in essence, is what the generic competition economic literature cited above has done. However, the availability of that same data provides a rich laboratory in which the effects of generic entry can be tracked first-hand. [redacted] REDACTED [redacted]

[redacted] REDACTED [redacted][74] The same approach is available here as a method of proving the likely impact of unimpeded generic entry.[75] This kind of evidence, like that discussed above, is common to all members of the Class.

One way to use this data would be to compare the experience of other drugs facing unimpeded generic competition with TriCor's experience given Abbott's alleged illegal efforts to limit the scope of generic competition. The actual market entry dates for various dosage strengths of TriCor were:[76]

| | 67 mg | 134 mg | 200 mg |
|---|---|---|---|
| Generic Capsules: | | | |
| Teva | 1/03 | - | 5/02 |
| Gate | 10/02 | 9/02 | 9/02 |
| Impax | - | - | - |

| | 54 mg | 160 mg |
|---|---|---|
| Generic Tablets: | | |
| Gate | 12/05 | 12/05 |

[74] [redacted] REDACTED [redacted] See Abbott_Tricor0000938-946, Abbott_Tricor00016645, Abbott_Tricor00012720 and Abbott_Tricor00000938-946.

[75] [redacted] Abbott_Tricor00000939. [redacted] in performing any analysis to determine common, classwide impact, appropriate adjustments would have to be made to ensure that the rate of generic penetration is suitably reflective of prevailing rates at the relevant times in this case.

[76] Based on IMS data.

Abbott transactional data produced in this case for the period beginning with this (allegedly impeded) generic entry could then be contrasted with the experience of other brands (specifically, as one possibility, the brands Abbott used in its own effort to project the likely consequences of unimpeded generic competition on Tricor). While I have not yet performed this particular analysis, I fully expect it will show that Abbott has been strikingly successful in holding onto brand revenues and margins and profits. Such success would square well with Plaintiffs' claim that anticompetitive activity has successfully forestalled generic competition. That evidence would be common to all members of the proposed Class.

**D. The Economic Role of Class Members**

From my review of Abbott's computerized sales database, and Mr. Fiske's testimony, it appears that the direct purchasers of TriCor from Abbott were primarily wholesalers, retail pharmacies, and managed care organizations.[77] These entities all serve broad cross-sections of the patient community.

As explained above, the impact of the conduct at issue in this case would have been to forestall what would otherwise have been a broad market-

[77] The identity and number of direct purchasers of Abbott's TriCor should be easy to identify from Abbott's transactional sales records. [redacted] I am consulting to process and analyze the data. Mr. Fiske testified that [redacted] Fiske Deposition, pp. 140-41.

REDACTED

wide shift from TriCor to lower-priced AB-rated generic versions of fenofibrate, as well as increased discounts on those portions of Class members' fenofibrate purchases that remained with the brand. Suppose that the shift to AB-rated generics--which would have occurred but for the allegedly illegal behavior--represented 70%-80% of Abbott's TriCor prescriptions.[78] Purely as a matter of statistical probabilities, there is a very high likelihood that proposed Class members buying product directly for various cross-sections of customers within the market would have had at least some need (and likely a significant need) to purchase the AB-rated generics.[79] Indeed, even before finding out what would happen among their customers, Class members (who by definition already buy branded TriCor) would have to buy at least some AB-rated generic to be ready to meet their customer needs. Moreover, given the likelihood (based upon the past history of brand pricing responses to generic competition) that at least some of the branded TriCor that would have continued to be sold would have carried higher discounts, there remains a likelihood of antitrust impact even as to the unlikely direct purchaser that wouldn't have purchased any generic in a fully competitive world.

[78] A figure broadly consistent with actual experience when generic competition operates freely.
[79] To illustrate, if every prescription has an independent 70% probability of becoming generic, the likelihood that a direct purchaser/reseller handling 1000 prescriptions would require no generic is $(.3)^{1000}$, which is well below one in a million. Even with 50 prescriptions, the probability is still less than one in a million. While the independence assumption underlying these probabilities may not hold strictly, there is no reason to believe here that direct purchasers are segmented in their customer segments in a way that would somehow align with non-generic consumers.

Accordingly, this evidence about the economic role of class members, combined with the other evidence described above regarding the broad and deep market impact of unimpeded generic entry would demonstrate that, with a high degree of likelihood, most all or all class members suffered antitrust impact. As with the other evidence described above, this evidence would be common to the class.

## VI. Classwide Analysis of Damages

Plaintiffs' claims for damages in this case constitute the overcharges associated with the higher prices direct purchasers paid for branded (and generic) TriCor during the period over which generic competition was allegedly impaired by Defendants' alleged scheme, and for some period thereafter until the competitive process reaches the equilibrium it would have achieved had generic competition not been impaired.

The classwide aggregate "overcharge" here stems from the following three potential sources. First, because of the impairment of generic competition from Defendants' scheme, Class members purchased higher-priced branded TriCor instead of the less-expensive AB-rated generic versions of TriCor. This elimination (or at least substantial suppression) of substitution of AB-rated generics for brand is what I refer to as "Brand-Generic" or "BG" overcharges. The second source of overcharge is the failure of Class members

to realize the effects of unimpeded generic competition on branded TriCor pricing. This reflects the difference between lower discounted branded TriCor prices that certain purchasers would have received given unimpaired generic competition versus actual prices paid for TriCor ("Brand-Brand" or "BB overcharge).[80] The third source of overcharge relates to purchases of the AB-rated generic. Unfettered AB-rated generic competition from multiple generic manufacturers puts competitive pressure on the price of the generic, leading to further generic price reductions. Thus, the impairment of AB-rated generic TriCor competition due to Defendants' alleged scheme caused (and will cause) Class members to pay more for the few generic purchases they did make ("Generic-Generic" or "GG" overcharges), and to pay more for the increased generic purchases that they will make if and when generic impairment subsides. In sum, these three sources of overcharges share in common the fact that the impairment of generic competition prevented Class members from realizing lower prices both by impeding their substitution to less expensive generics and by forestalling price decreases for both the brand and the corresponding AB-rated generic form of TriCor.

[redacted]

REDACTED

[redacted] Abbott_Tricor00005639.

These overcharges can be assessed readily through class-wide, aggregate damage models utilizing formulas and methodologies that do not require individualized analysis. Indeed, much of the same common evidence that I would rely upon to establish classwide impact—the published literature, the various sales and generic competition forecasts, and the models similar to those Defendants themselves used to assess the effects of impeded and unfettered generic competition—can be used to develop benchmarks for pricing and generic penetration for fenofibrate had AB-rated generic competition not been impaired.

There is at least one published study that actually quantifies the additional costs, in aggregate, associated with the impairment of generic competition to various levels of the market. The study analyzed the impact on purchasers of a delay in generic competition from the drug, Taxol. The authors summarized the results as follows:

> If [Taxol's manufacturer] receives a two-year extension of its exclusivity beyond the current expiration date. . . consumers, insurers, and the government will incur significant costs. We estimate these costs in present value terms as:
>
> - $1.09 billion based on prices charged by sellers to intermediaries
> - $1.27 billion based on prices charged by intermediaries to final payers
> - $288 million for Medicare alone.[81]

[81] Rozek, et al., *The Costs to the U.S. Health Care System of Extending Marketing Exclusivity for Taxol®*. Note that this study pertains to a delay of generic competition, this case presents the

I take further confidence in the ability to measure aggregate overcharges associated with limits on generic entry using class-wide analysis from the fact that I have done so on several prior occasions. In particular, I have done so in connection with generic-related claims of antitrust overcharges for direct purchaser classes of the branded products Cipro, Hytrin, Cardizem, Buspar, Platinol, Relafen, and Remeron. In several of these cases, the aggregate damage analysis I performed served as the basis for the Court's review and approval of class-wide settlements. My review of the facts in this case reveals nothing to indicate that overcharges will not be similarly susceptible to class-wide measurement.

The method for measuring the overcharge, in essence, involves, first, the development of a benchmark for market performance—the "but-for world"—reflecting the world as it would have been had generic competition not been impaired by Defendants' alleged scheme (as Plaintiffs allege). The next step involves a comparison of the Class members' aggregate expenditure costs for the drug (including both branded and generic forms) as between their actual experience and the experience they would have had in the but-for world. One may develop the but-for world based upon empirical data from a comparable generic product, or a sampling of other branded drugs that have faced generic competition in the market [redacted] REDACTED [redacted] One can

alleged impairment of generic competition, where the impairment, and thus the associated aggregate overcharge, is not delimited by time and thus is not finite.

also model the but-for world using an analysis keyed to Defendants' (or Teva's or Impax's) projections. Either or both approaches are reasonable and reliable. I have successfully used both approaches in the past.

With the but-for world in place, the rest is mostly arithmetic. It involves a sum, in the aggregate, of: 1) the difference between the generic price and the brand price multiplied by the volume of generic substitution by the Class that was forestalled by the impairment of generic competition; 2) the inflated amounts paid by the Class for the branded volumes it still would have purchased even if generic competition had occurred unimpaired (attributable to unrealized generic price competition); and 3) the inflated amounts paid by the Class for generic volumes attributable, again, to unrealized generic price competition.

I am signing this Declaration under penalty of perjury.

5/8/06
Date

Jeffrey J. Leitzinger, Ph.D.